

E3 11. A process for preparing a beneficial microorganism propagation-promoting material according to claim 5 wherein said water added to said resultant is added until a content of said water is 50% by weight.--

### REMARKS

Applicant has amended claims 1, 2 and 5 and added new claims 9-11. Applicant respectfully submits that the amendments to the claims are supported by the application as originally filed and do not contain any new matter. Accordingly, the Office Action will be discussed in terms of the claims as amended.

The Examiner has rejected claims 1, 2, 4, 5 and 7 under 35 USC 112, second paragraph, as being indefinite, stating that claims 1, 2 and 5 are indefinite with regard to several concepts related to the claimed terms "koji", "solid form", "grains", "50% by weight of water", "beneficial microorganisms" and "phytic acid".

In reply thereto, Applicant respectfully submits that the term "koji" is clearly defined at page 12, lines 12-15 of Applicant's application. The term "grains" is defined in Japanese Laid-Open H7-23725 which is incorporated by reference in Applicant's application. The term "50% by weight of water" has been amended to clarify Applicant's invention. The term "beneficial microorganism" is defined at page 1, lines 14-15 and the term "phytic acid" is defined at page 12, lines 28-31 of Applicant's application. Still further, as to the term "resistant starch", Applicant respectfully submits that the previously submitted information clearly defines the resistant starch. Additionally, Applicant respectfully submits that while Applicant's definition of "resistant starch" is not much different from 'Merck's definition of a generic starch', the resistant starch is an essential element of Applicant's claim 2 and cannot be ignored. Also, Applicant respectfully submits that the term "solid form" indicates that the grains are in a form in which they have not been ground, pulverized or powdered and each of the grains as defined in Japanese Laid-Open H7-23725 which corresponds to U.S. Patent No.

5,853,779 retains its integrity.

In addition and as to claims 4 and 7, Applicant respectfully submits that Eumycetes do not include koji mold or Aspergillus and are meant to include such fungi or mold as yeast, etc. as defined at page 1 of Applicant's application. Still further, Applicant

respectfully submits that the lactic acid bacteria and the bifidobacteria as further claimed in Markush group of claims 4 and 7 are separate and distinct.

In view of the above, therefore, Applicant respectfully submits that claims 1, 2, 4, 5 and 7 are distinct and comply with 35 USC 112, second paragraph.

The Examiner has rejected claims 1, 2 and 4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161.

*not true  
"completion  
of  
hydrolysis"  
Col. 7.*

Applicant has carefully reviewed the '161 patent and respectfully submits that claims 1-9 do not show or suggest Applicant's claims 1, 2 and 4. In particular, Applicant respectfully submits that none of claims 1-9 discloses the decomposition of phytic acid in the cultivation process. Still further, Applicant respectfully submits that none of claims 1-9 of the '161 patent discloses the addition of a beneficial microorganism to the koji mold or that the product would contain a substance that would remain undigested up to the colon and that the undigested product would promote propagation of lactic acid bacteria in the intestines. ✓ ✓ ✓

*DP*

In view of the above, therefore, Applicant respectfully submits that claims 1, 2 and 4 are not improperly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161.

The Examiner has further rejected claims 5 and 7 provisionally under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 6-10 of copending application No. 09/284,935 which is a divisional application No. 09/194,657, now U.S. Patent No. 6,303,161.

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In reply thereto, Applicant respectfully submits that application No. 09/284,935 is the parent of the present CPA application and the present application is a continuing patent application thereof as is admitted by the Examiner in the opening paragraph of the Office Action. Still further, Applicant respectfully submits that application No. 09/284,935 is not a divisional application of application No. 09/194,657, now U.S. Patent No. 6,303,161. Therefore, Applicant respectfully submits that this provisional rejection under the judicially created doctrine of obviousness-type double patenting is improper. ?

*DP*

The Examiner has rejected claims 1, 4, 5 and 7 under 35 USC 102 as being

anticipated by U.S. Patent No. 5,885,632, stating that the '632 patent teaches a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains or crops such as soybeans with koji mold to create a koji preparation resultant, adding water to the resultant and removing phytic acid wherein hydrolysis of the resultant is obtained by action of beneficial microorganisms contained in the resultant such as *Eumycetes* or fungal cultures or various koji molds.

In reply thereto, Applicant has carefully reviewed the '632 patent and respectfully submits that at col. 6, lines 43-45 and particularly lines 38-46 it describes the koji starter and not the beneficial microorganism. Clearly, in the '632 patent only a koji mold starter is utilized and it does not disclose a beneficial microorganism such as *Eumycetes*, lactic acid bacteria or bifidobacteria. Still further, Applicant respectfully submits that in the '632 patent the phytic acid is reduced by hydrolysis and not by the cultivation. Finally, Applicant respectfully submits that the '632 patent does not teach a product which contains a substance that remains undigested to the colon and that such substance would promote the propagation of the beneficial microorganism in the intestines.

In view of the above, therefore, Applicant respectfully submits that claims 1, 4, 5 and 7 are not anticipated by the '632 patent.

The Examiner has rejected claims 1, 4, 5 and 7 under 35 USC 102 as being anticipated by U.S. Patent No. 4,308,284 in light of evidence provided by the teachings of U.S. Patent No. 5,885,632 or JP 7-23725, stating that the '284 patent clearly teaches a process and a product obtained by the process comprising the steps of inoculating grains or crops with koji mold belonging to *Aspergillus*, adding water and beneficial microorganisms such as lactic acid bacteria and the step of removing phytic acid which is contained in the grains or hydrolyzed resultant is inherently present in the method/composition obtained by the method of the '284 patent in light of evidence taught by the '632 patent or JP '725.

In reply thereto, Applicant respectfully submits that for a reference to be prior art under 35 USC 102 so as to negate the novelty of an invention, the prior art reference must disclose and show each and every element of the invention within its four corners and the use of inherency from other references is improper under 35 USC 102, namely novelty.

Applicant has further carefully reviewed the '284 patent and respectfully submits

that the process disclosed therein is for making a koji which is utilized in the manufacture of soy sauce and while it may disclose the utilization of lactic acid bacteria and yeast, this is only for the purposes of shortening the aging period of the moromi liquid. Finally, Applicant respectfully submits that the '284 patent does not disclose anything about producing a substance that remains undigested up to the colon and that such substance would promote the propagation of lactic acid bacteria in the intestines.

In view of the above, therefore, Applicant respectfully submits that claims 1, 4, 5 and 7 are not anticipated by U.S. Patent No. 4,308,284.

The Examiner has rejected claims 1, 4, 5 and 7 under 35 USC 102 as being anticipated by U.S. Patent No. 5,965,178 in light of evidence provided by U.S. Patent No. 5,885,632 or JP 7-23725, stating that the '178 clearly teaches a process and a product obtained by the process comprising the steps of inoculating grains or crops such as soybean or rice or wheat with koji mold belonging to *Aspergillus*, adding water and beneficial microorganisms such as lactic acid bacteria and the step of removing phytic acid from the grains is inherently present in the method/composition obtained by method of the '178 patent in light of evidence as taught by U.S. Patent No. 5,885,632 or JP 7-23725.

In reply thereto, similarly to the above, Applicant would like to point out that novelty requires that all of the elements of the claimed invention be contained within the four corners of a single reference and the implication or inherency cannot be found outside of the reference. Therefore, Applicant respectfully submits that the '178 patent has no effect on the novelty of Applicant's invention.

Still further, Applicant has carefully reviewed the '178 patent and respectfully submits that there is absolutely nothing contained therein concerning the decomposition of phytic acid. Still further, Applicant respectfully submits that the '178 patent discloses a hydrolyzate seasoning which is prepared from koji. Still further, Applicant respectfully submits that the '178 patent teaches nothing about producing a material containing a substance that remains undigested up to the colon and that such a substance would promote the propagation of lactic acid bacteria in the intestines.

In view of the above, therefore, Applicant respectfully submits that claims 1, 4, 5 and 7 are not anticipated by U.S. Patent No. 5,965,178.

The Examiner has rejected claims 1 and 5 under 35 USC 102 as being anticipated by U.S. Patent No. 4,329,370 in light of evidence provided by U.S. Patent No. 5,885,632 or JP 7-23725, stating that the '370 discloses a process and a material obtained by the process wherein the process encompasses steps of inoculating solid form of grains with koji mold to create a koji preparation resultant, adding water or suspension with beneficial bacteria to the resultant and removing phytic acid and the step of removing phytic acid from the grains is inherently present in the method/composition obtained by the method of the '370 patent in light of evidence provided by the '632 patent or JP '725.

In reply thereto, Applicant would like to again point out that for a novelty rejection all of the elements of the claims must be disclosed within the four corners of the applied reference and inherency or implication is immaterial. Still further, Applicant respectfully submits that a review of the '370 patent indicates that there is no mention of the phytic acid or a requirement of removing it.

Additionally, Applicant has carefully reviewed the '370 patent and respectfully submits that it is for a process for producing a solid koji which is suitable for use in the manufacture of fermented food products such as soy sauce, miso, sake and miran. In contrast thereto, Applicant's invention is for a material which contains a substance that remains undigested up to the colon and such substance promotes the propagation of lactic acid bacteria in the intestines. Clearly, the '370 patent does not perform this function. Also, Applicant has carefully reviewed col. 8, lines 22-25 and respectfully submits that it merely teaches "various bacteria separated from an ordinary soy sauce koji uniformly sprayed onto the substrate" and nowhere does it teach anything about beneficial bacteria or lactic acid bacteria. In addition, Applicant respectfully submits that the goal of providing a material which makes it possible to inhibit growth of contaminating bacteria makes it unlikely that one would add a beneficial bacteria such as lactic acid bacteria since it too would most likely be inhibited.

In view of the above, therefore, Applicant respectfully submits that claims 1 and 5 are not anticipated by U.S. Patent No. 4,329,370.

The Examiner has rejected claims 1, 2, 4, 5 and 7 under 35 USC 103 as being obvious over U.S. Patent Nos. 5,885,632 or 4,308,284 or 5,965,178 or 4,329,370 in light

of U.S. Patent No. 5,885,632 or JP 7-23725 taken with U.S. Patent No. 5,118,626, Remington, Merck and JP 3-19686.

In reply thereto, Applicant would like to incorporate by reference her comments above concerning several of these references and Applicant's invention. Still further, Applicant respectfully submits that the Examiner has essentially put together an almost unintelligible or unanalyzable rejection. Also, Applicant respectfully submits that since the Examiner has had to select from so many different references in so many different combinations, one of ordinary skill in the art would not know how to make such a selection. Finally, Applicant respectfully submits that the selection required to produce Applicant's invention from the various arts relied upon by the Examiner can only be done utilizing hindsight and hindsight is improper.

In view of the above, therefore, Applicant respectfully submits that claims 1, 2, 4, 5 and 7 are not obvious over the various references relied upon by the Examiner in the various combinations suggested by the Examiner.

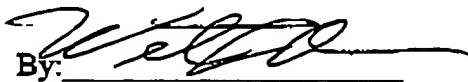
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

In view of the above, therefore, it is respectfully requested that this Amendment be entered, favorably considered and the case passed to issue.

Please charge any additional costs incurred by or in order to implement this Amendment or required by any requests for extensions of time to KODA & ANDROLIA DEPOSIT ACCOUNT NO. 11-1445.

Respectfully submitted,

KODA & ANDROLIA

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William L. Androlia

Name



Signature

5/7/2002

Date

Application No. 09/284,935

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claim 1 (thrice amended) has been amended as follows:

1. (Four Times Amended) A beneficial microorganism propagation-promoting material which promotes propagation of a beneficial microorganism in a colon of a living being that helps to sustain the health of living beings, said material comprising a substance that remains undigested up to the colon, said material being obtained by steps of:

cooking solid form grains,

cooling the solid form grains to a temperature at which koji mold propagates,

inoculating koji mold on solid said form grains to create a koji preparation resultant,

adding [a maximum of 50% by weight of] water to said resultant to [thereby] hydrolyze proteins and/or saccharides contained in said resultant,

during said hydrolysis said koji mold and beneficial microorganisms contained in said resultant and/or added to the resultant [are] being symbiotic in the resultant and propagation of said beneficial microorganisms [is] being promoted when the beneficial microorganisms receives nutrients from the resultant so that said koji mold and said beneficial microorganisms are cultivated together in said resultant, and

[removing] decomposing a predetermined amount of phytic acid contained in said grains during cultivation of said koji mold.

Claim 2 (thrice amended) has been amended as follows:

2. (Four Times Amended) A beneficial microorganism propagation-promoting material that contains a substance that remains undigested up to a colon of a living being, said material obtained from the steps comprising:

mixing together a product for promoting propagation of beneficial microorganisms and a resistant starch; and wherein

said product for promoting propagation of beneficial microorganisms that help to [subtain] sustain the health of living beings is obtained by:



cooking solid form grains;

cooling the solid form grains to a temperature at which koji mold propagates;

inoculating koji mold on said solid form grains to create a koji preparation resultant,  
adding [a maximum of 50% by weight of] water to said resultant to [thereby] hydrolyze  
proteins and/or saccharides contained in said resultant,

during said hydrolysis said koji mold and said beneficial microorganisms contained in  
said resultant and/or added to the resultant [are] being symbiotic in the resultant and propagation  
of said beneficial microorganisms [is] being promoted when said beneficial microorganisms  
receive nutrients from the resultant so that said koji mold and said beneficial microorganisms are  
cultivated together in said resultant, and

[removing] decomposing a predetermined amount of phytic acid contained in said grains  
during cultivation of said koji mold; and

said resistant starch becomes a nutrient of lactic acid bacteria that grows in the intestines  
of animals.

Claim 5 (thrice amended) has been amended as follows:

5. (Four Times Amended) A process for preparing a beneficial microorganism  
propagation-promoting material which promotes propagation of a beneficial microorganism that  
helps to sustain the health of living beings and that contains a substance that remains undigested  
up to the colon, said process comprising the steps of:

cooking solid form grains;

cooling the solid form grains to a temperature at which koji mold propagates;

inoculating koji mold on said solid form grains to create a koji preparation resultant,  
adding [a maximum of 50% by weight of] water to said resultant to [thereby] hydrolyze  
proteins and/or saccharides contained in said resultant,

during said hydrolysis said koji mold and said beneficial microorganisms contained in  
said resultant and/or added to said resultant [are] being symbiotic in the resultant and propagation  
of said beneficial microorganisms [is] being promoted when said beneficial microorganisms  
receive nutrients from said resultant so that said koji mold and said beneficial microorganisms  
are cultivated together in said resultant, and

[removing] decomposing a predetermined amount of phytic acid contained in said hydrolyzed proteins and/or saccharides during cultivation of said koji mold.

Add new claims 9-11 as follows:

--9. A beneficial microorganism propagation-promoting material according to claim 1 wherein said water added to said resultant is added until a content of said water is 50% by weight.

10. A beneficial microorganism propagation-promoting material according to claim 2 wherein said water added to said resultant is added until a content of said water is 50% by weight.

11. A process for preparing a beneficial microorganism propagation-promoting material according to claim 5 wherein said water added to said resultant is added until a content of said water is 50% by weight.—